

#### 4. Special Marketing Restrictions for Endorsed Sponsors

Under the Medicare drug discount card program, as explained above, endorsed sponsors will be required to provide information and outreach about products and services offered under the endorsement. Section 1860D–31(h)(7)(B) of the Act provides that an endorsed sponsor may only market those products and services directly related to a covered discount card drug, or discounts for non-prescription drugs to the extent such marketing is otherwise permitted under the Medicare drug discount drug card program and the Privacy Rule. Accordingly, § 403.813(a)(1) provides that an endorsed sponsor may only market those products and services offered within the scope of its endorsement, that is, products and services directly related to a covered discount card drug, and discounts for non-prescription drugs. Thus, only products and services offered by an endorsed sponsor within the scope of its endorsement may be included in an endorsed sponsor's information and outreach materials.

As discussed in section II.C.5. of this document, products or services offered by an endorsed sponsor following termination of its endorsement or termination of the Medicare drug discount card program are considered outside the scope of endorsement. Therefore, § 403.813(b)(4) of our regulations provides that individually identifiable health information created, collected or maintained by an endorsed sponsor may not be used to market any product or service following termination of an endorsed sponsor's endorsement or the program.

Under the Privacy Rule, most uses or disclosures of protected health information to make marketing communications require individual authorization. The Privacy Rule at 45 CFR 164.501, however, defines the term "marketing" to mean the making of a communication about a product or service that encourages the recipient of the communication to purchase or use the product or service, with the exception of communications that—

(1) Describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication;

(2) Are for treatment of the individual; or

(3) Are for case management or care coordination, or to direct or recommend alternative treatments, therapies, health

care providers, or settings of care to the individual.

Since information and outreach under the Medicare drug discount program is limited to communicating about products and services offered within the scope of endorsement, these activities fall within the exception to the definition of marketing under the Privacy Rule for describing health-related products or services provided by the covered entity. Thus, using or disclosing beneficiary protected health information to provide information and outreach is not marketing under the Privacy Rule, but rather, as described above, is permitted without beneficiary authorization as part of the endorsed sponsor's health care operations.

To use or disclose protected health information to make communications that do not fall within the exceptions to the definition of "marketing" under the Privacy Rule at 45 CFR 164.501, a covered entity must obtain individual authorization in accordance with 45 CFR 164.508(a)(3). However, section 1860D–31(h)(7)(B) of the Act limits the marketing that may be conducted by endorsed sponsors to only that which pertains to products and services offered under the Medicare drug discount program or discounts on over-the-counter drugs. For purposes of this marketing prohibition, we will consider a communication to be marketing if the communication is about a product or service and encourages recipients of the communication to purchase or use the product or service. Thus, a sponsor may not market if the marketing involves products or services falling outside the endorsed sponsor's endorsement, that is, services that do not directly relate to a covered discount card drug, or to discounts for a non-prescription drug. Section 403.813(a)(2) of our regulations expressly provides that an endorsed sponsor may not request of a drug card applicant or enrollee the use or disclosure of protected health information to market any products or services not offered under the program. Thus, endorsed sponsors may not market such products or services under § 403.806(d)(3) of our regulations even if they obtain authorization from discount card enrollees to do so, as permitted by the Privacy Rule. Due to this prohibition, endorsed sponsors are not permitted, at the time of enrollment or any other time, to ask beneficiaries if they would be interested in receiving marketing materials related to products and services offered outside the program. Similarly, endorsed sponsors may not commingle any information and outreach materials that describe their endorsed program with any

marketing materials related to products and services offered outside the program.

This prohibition applies regardless of whether the marketing of products or services outside the program involves the use or disclosure of protected health information of discount card enrollees. Accordingly, marketing of a product or service outside the program that does not involve the use of discount card enrollees' protected health information, such as advertising for contact lenses or travel on an endorsed sponsor's Web site, is not permitted under the Medicare drug discount card program, even though such marketing would not involve the use of protected health information.

Many entities that sponsor an endorsed program also may engage in activities outside the Medicare drug discount card program. For example, a Part C organization may be both a sponsor of an endorsed program and operate a Part C plan. The marketing prohibition set forth under section 1860D–31(h)(7)(B) of the Act only applies to entities when acting in their capacity as an endorsed sponsor. Accordingly, although an entity in its endorsed sponsor capacity may not commingle with other marketing materials any information and outreach materials related to products and services offered under its endorsed program, it may commingle such materials when acting in another capacity, to the extent otherwise permitted under law. For example, a Part C organization which sponsors an endorsed program may, in its role as a Part C plan, commingle information and outreach materials describing its endorsed program with Part C plan marketing materials to the extent permitted under the Privacy Rule and the Part C marketing rules under Medicare Part C. We will deem an entity as acting in its capacity as an endorsed sponsor when it either (1) uses beneficiaries' information created, collected or maintained under its endorsed program to conduct marketing, or (2) targets its marketing to all or a subset of its discount card enrollees (or potential discount card enrollees). We will deem an entity as acting in another capacity when it (1) does not use beneficiaries' information created, collected or maintained under its endorsed program to conduct marketing, and (2) does not target its marketing to all or a subset of its discount card enrollees (or potential discount card enrollees). For example, we will consider a Part C organization as acting in its endorsed sponsor capacity if it targets its marketing to members of its